

REMARKS

The drawings were objected to because several reference characters have been used to designate more than one component. FIGS. 7-10, 12, 14 and 15 have been corrected herein to have each reference character designate only one component and to have the designations consistent through all of the figures. Enclosed herewith are FIGS. 7-10, 12, 14 and 15, in duplicate, with a Letter to the Official Draftsman showing the corrections in red and also with the formal drawings incorporating the corrections.

A review of the specification indicated that several reference characters were incorrectly designated. The specification has been amended herein to be consistent throughout and also to correspond with the corrected drawings.

Claims 1-17 have been cancelled herein without prejudice or disclaimer reserving the right to file a continuation application or take other steps to preserve the novelty of the invention recited therein.

Claims 14-17 were objected to for informalities. Claims 4, 6, 13-17 were rejected under 35 U.S.C. 112, second paragraph. Claims 1-12 were rejected under 35 U.S.C. 101. Claim 14 was rejected under 35 U.S.C. 102(b). Claims 1-17 were rejected under 35 U.S.C. 102(a) as being unpatentable over one or more cited references. These issues are now moot since claims 1-17 have been cancelled.

New claims 18 and 19 have been inserted herein. The informalities and bases of rejection stated in the Official Action have been considered in drafting of the new claims.

The present invention is directed to a tracheostomy tube mounted in a neck plate which has integrally molded bands attached to the neck plate. One band is longer than the other band as shown in FIG. 15. A connector is provided to rapidly connect and disconnect the bands together so the neck plate and cannula can be comfortably fitted to the neck of the patient. Because of the uneven length of the bands, the connector is disposed on the side of the neck of the patient (FIGS. 7, 9 and 11). Thus, as contrasted to the prior art the device of the present invention is mounted on the patient without lifting the patient's head which is painful to the patient.

The neck plate and the bands are formed as a unitary item from a viscoelastic polymer which is adapted to itself to the anatomy of the patient and, hence, is very comfortable and non-irritating. The viscoelastic polymer has been used by surgeons as a support pad for many years and is approved for use in healthcare facilities. The device also has an adjustment means to provide for shortening or lengthening the band for increased patient comfort. In addition, the neck plate is wider than the bands and blends in a curved transitional manner with the bands as shown in FIG. 15. (See color marked drawing attached)

Wapner discloses a band for supporting tracheostomy tubes which has a neck plate. Two bands are provided which are not integrally molded to the neck plate. The two bands are formed from an outer layer of non-stretchable cotton and an inner layer of a sponge-like non-stretchable substance. The bands each have a Velcro strap which is threaded through an opening in the neck plate (column 2, lines 24-37). In assembly, the straps must be inserted in the openings, folded and secured. One of the bands has an elastic webbed section which is connected by Velcro to the end of the other band. As noted on column 2, line 2 through column 3, line 3, the elastic band is stretchable

but does not provide a great deal of stretch. The reference does not suggest nor disclose any viscoelastic polymer construction. The bands of *Wapner* are wider than the neck plate as shown in FIGS. 1 and 2. In use the attendant must proceed through a series of steps (column 3, lines 14-22) which require time and may discomfort the patient. *Wapner* does not disclose or suggest a rapid connector means as claimed by the applicant.

Tuman discloses an endotracheal tube support device. This device is not for a tracheostomy tube for the patient's neck but secures a tube in the vicinity of the patient's nose or mouth (column 2, lines 45-47). This is further shown in FIG. 2. A strap is formed from a rayon/nylon material. The reference does disclose a quick release connector. However, it is submitted that the device is not for a tracheostomy tube and there is no suggestion or disclosure that the device has application beyond the endotracheal use. There is no motivation for a person of ordinary skill in the art of tracheostomy to consider devices for endotracheal tubes and apply the devices to tracheostomy.

Belfer et al disclose a strapless respiratory facial mask which has a thermoplastic material around the edges. The elastomeric cushioning material is used for peripheral sealing (column 10, lines 39-40). There is no suggestion nor disclosure that the entire facial mask be formed from the elastomeric material. Further, it is submitted that persons of ordinary skill in the art of tracheostomy have no motivation to consider respiratory facial masks.

Lane discloses a helmet and face mask interface system which has an adjustment means to adjust a strap which holds the helmet to the mask. There is no suggestion or disclosure that the system be used with a tracheostomy tube. There is no motivation for persons of ordinary skill in tracheostomy to be aware of, or consider, the helmet and face mask of *Lane*.

The Examiner has cited and relied upon a number of references from diverse technologies which are unrelated to the present field of tracheostomy and which consequently offer no teachings of applicable merit to those of ordinary skill in the art of tracheostomy. There is no teaching or suggestion in the cited references of how the art would be applied to the field of tracheostomy. Rather, it is only coincidental that there are a few isolated features which resemble those recited in the present claims. However, the cited references are without the common purpose, benefits and advantages attained by the present invention. It is respectfully requested that the Examiner reconsider the applicability of these references to the present rejection, since these are not a part of, or in any remote way related to, the field of the present invention, nor is there any teaching, suggestion or motivation apparent therein which would suggest that one of ordinary skill in the field of tracheostomy would look to these documents for teachings applicable to tracheostomy. The present invention and those references are, in fact, wholly unrelated in the determination of the scope and contents of the relevant prior art.

It is further submitted that not only is there no motivation to combine the cited references but even if combined, the resulting device would have a more narrow neck piece connected by wider straps with Velcro attachment to a fabric band. The neck piece would have a peripheral seal of elastomeric material. The neck piece would not be integral with the bands and would not be formed from a elastomeric material. In use, the straps would need to be threaded through the openings in the neck piece and the bands disposed around the neck of the patient. It would then have to be adjusted for the comfort of the patient. This would take time while working on a seriously ill patient. Even slight movement of the endotracheal tube in the incision in the patient's throat is painful. The cited

references, or a device resulting from the combination thereof, due to their very nature, would cause discomfort, if not pain, to the patient. The present invention is very simple to install, taking much less time, and the material of construction significantly reduces movement of the endotracheal tube. The present invention provides significant improvement to the health and comfort of the patient.

In addition, although *Wapner* has been known since 1982 and the viscoelastic polymer AKTON[®] identified by the applicant (page 8, line 3) has been commercially available since 1982 (as shown by the enclosed U.S. Trademark Registration No. 1,289,020) no one has combined these in any manner. Thus, contrary to the conclusion of the Examiner, there is no evidence that it was obvious to one of ordinary skill in the art to make the bands, and the neck piece, of the viscoelastic polymer or to form the bands integrally with the neck piece.

Also enclosed herewith is a Declaration from Alan H. Shikani, M.D. the inventor, based on his extensive clinical experience. The present invention has resulted from the deficiencies of the tracheostomy tubes and the mounting means which Dr. Shikani has experienced in his practice of otolaryngology. The Declaration explains how the present invention is an improvement in the state-of-the art. The Declaration also states that Dr. Shikani has an exclusive license agreement with Adam Spence Corporation. The fact that an organization of the stature of Adam Spence Corporation has entered into an exclusive license agreement is evidence that the present invention is not obvious to persons skilled in the art.

Claims 18 and 19 are currently pending in the application. The newly added claims replace original claims 1-17 and more specifically recite the fasteners and benefits of the present invention

that are novel. More particularly, the claims recite the neck piece integrally formed with the bands and made from a viscoelastic polymer.

In view of the recitations in each of the independent claims as now recited by the present Amendment, and the absence of such or teachings thereto in the prior art, the Examiner is respectfully requested to reconsider the rejection and pass this application to allowance. No new matter has been introduced in the present Amendment.

It appears that all matters have been addressed satisfactorily, and that the case is now in condition for a complete allowance; and the same is respectfully urged.

However, if the Examiner has any comments or questions, or has any suggestions as per MPEP 707.07 (d) and (j), for putting the case in condition for final allowance, she is respectfully urged to contact the undersigned attorney-of-record at the telephone number below, so that an expeditious resolution may be effected and the case passed to issue promptly.

Respectfully submitted,



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Oct 29, 2002

Date

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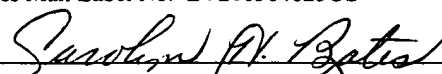
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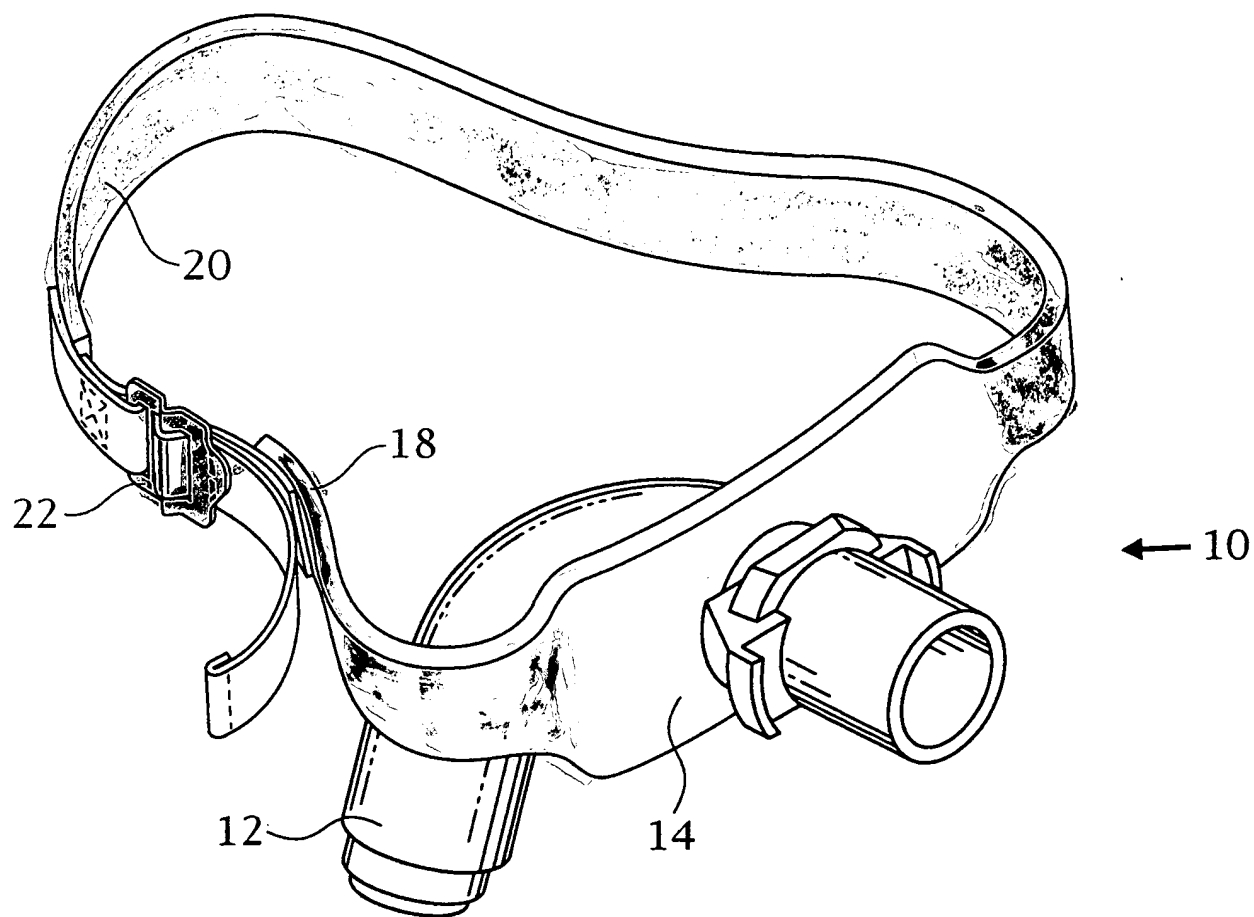


Fig 15



UNITED STATES PATENT AND TRADEMARK OFFICE

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Typed Drawing

Word Mark	AKTON
Goods and Services	IC 017. US 001. G & S: Viscoelastic Polymeric Material in Sheet Form and Cast Shapes for Use in Manufacture. FIRST USE: 19821026. FIRST USE IN COMMERCE: 19821026
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	73430287
Filing Date	June 15, 1983
Published for Opposition	May 15, 1984
Registration Number	1289020
Registration Date	August 7, 1984
Owner	(REGISTRANT) Action Products, Inc. CORPORATION DELAWARE 22 N. Mulberry St. Hagerstown MARYLAND 21740
Attorney of Record	Joseph P. Gastel
Type of Mark	TRADEMARK
Register	PRINCIPAL
Affidavit Text	SECT 15. SECT 8 (6-YR).
Live/Dead Indicator	LIVE

**VERSION WITH MARKINGS
TO SHOW CHANGES MADE
IN SPECIFICATION**

Page 6, lines 13-21

As shown in FIGS. 5 and 6, the present invention has a first band 18 connected to the neck plate 14 and a second band 20 connected to the opposite end of the neck plate 14. The end of the first band 18, distal from the neck plate 14, has a single means 22 for adjusting and connecting the bands 18, 20 attached thereto. FIGS. 6-9 show the tracheostomy tube of the embodiment of FIG. 6 of the present invention being attached to a patient. The cannula is received in the incision in the patient's throat and the bands 18, 20 are brought around the neck to meet on the side of the patient's neck. The distal end of the second band 20 is threaded through the adjusting means [20] 22 (see arrow FIG. 7) turned back on itself and re-threaded through the adjusting means (see arrow FIG. 8) to retain the tracheostomy tube 10 on the patient's neck and to connect the bands 18, 20. The adjusting

Page 7, lines 1-19

means 22 shown in FIGS. 6-9 also serves as a connecting means in that by drawing on the distal end of the second band 20 (see arrow FIG. 9) an increased length of the second band 20 is drawn through the [connector] adjusting means 22 and the bands are tightened around the patient's neck. In this manner the band is shortened until the patient is comfortable and the tracheostomy tube is retained on the patient. The adjusting means [24] 22 is not limited to the one shown in FIGS. 5-9 but may be any adjusting means [24] 22 known to persons skilled in the art which provides a simple and easily manipulated means to lengthen and shorten at least one of the bands (18, 20). The at least one band need not be formed of two segments but may be an uninterrupted band.

The adjusting means 22 and the connecting means 24 may be separated as shown in FIG. 10. The first band 18, second band 20 and adjusting means 22 are the same as shown in FIGS. 6-9. However, as noted above, the adjusting means [24] 22 is not so limited. A typical connecting means 24 has two releasable interlocking members which are quickly and easily connected and disconnected. Here, also, connecting means 24 known to persons skilled in the art may be used. It is preferred that one member of the connecting means 24 be attached to the distal end of the first band and the other member of the connecting means 24 be attached to the distal end of the second band 20. This does not preclude the connecting means 24 being disposed intermediately in one of the bands 18, 20. FIG. 11 shows the tracheostomy tube 10 of FIG. 10 mounted on a

supine patient with the connecting means 24 in a disconnected position. Pushing the two members together to connect the members is accomplished very rapidly without moving the cannula 12 and with no discomfort to the patient.

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Fig 7

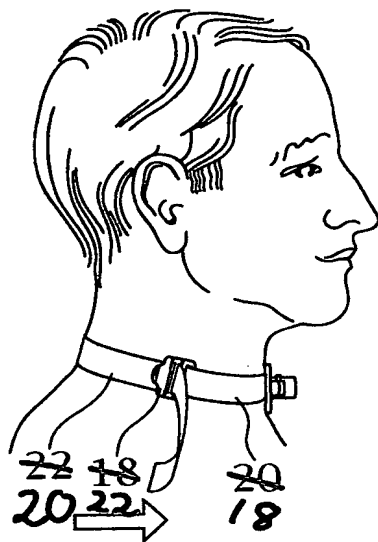


Fig 8

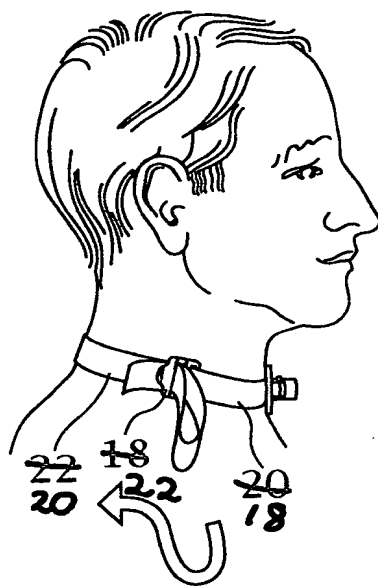
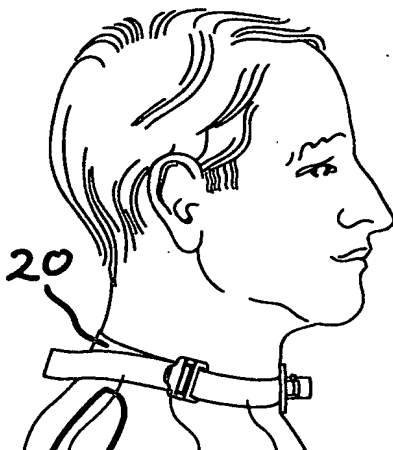


Fig 9



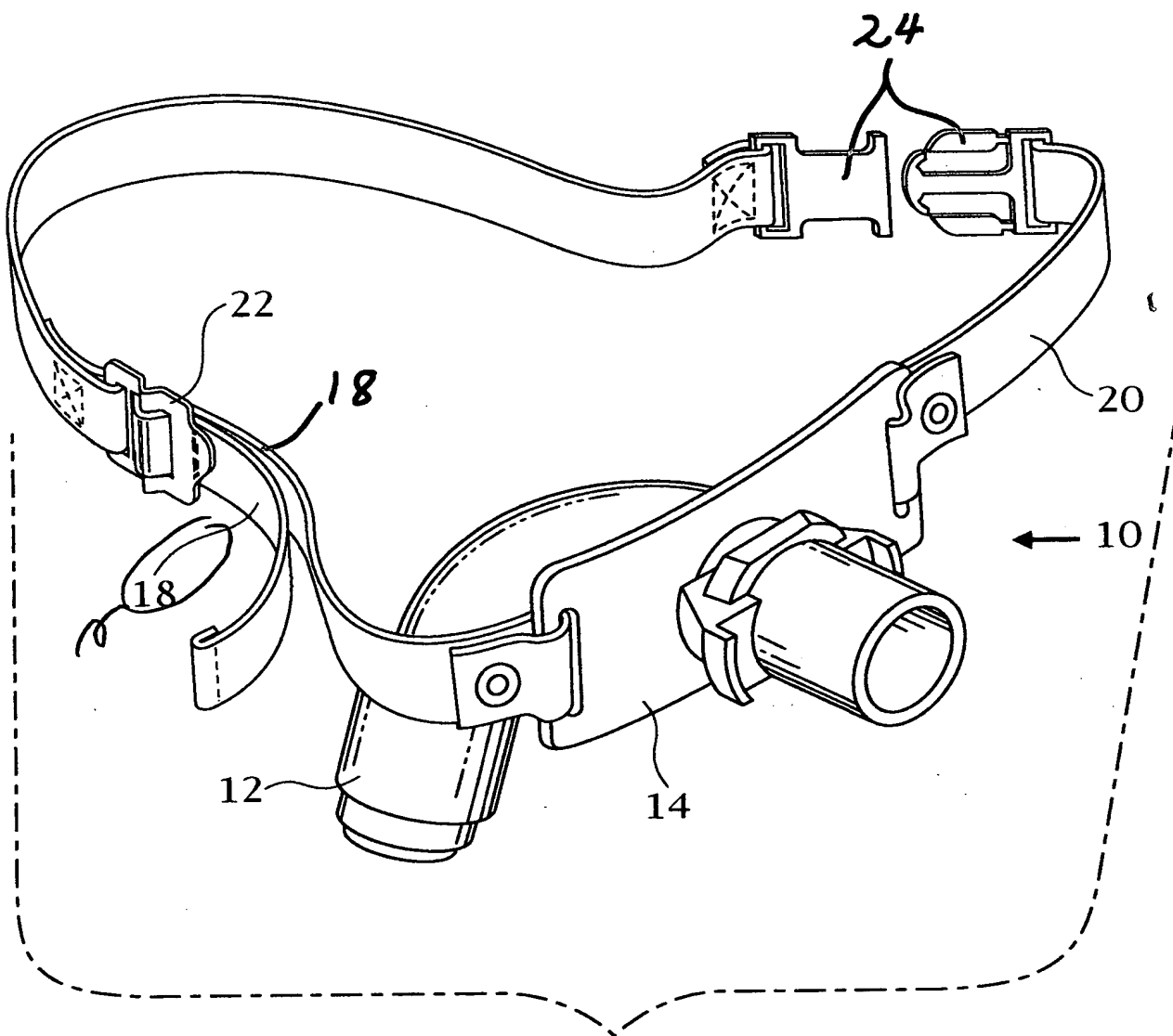


Fig 10

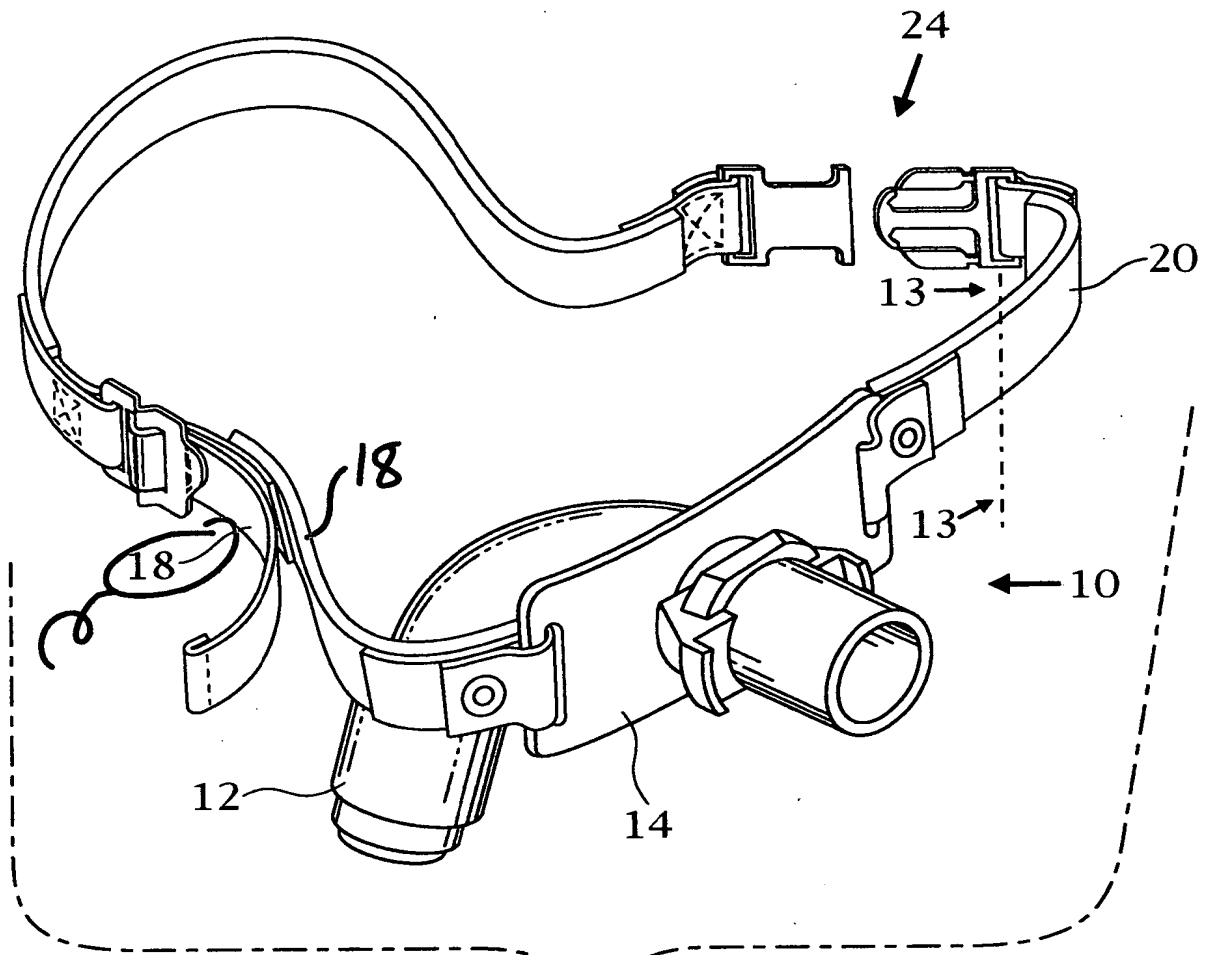
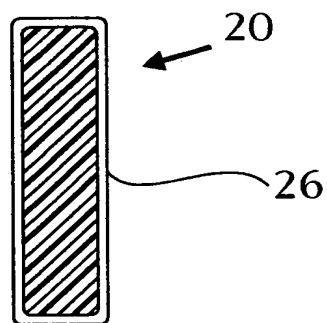


Fig 12



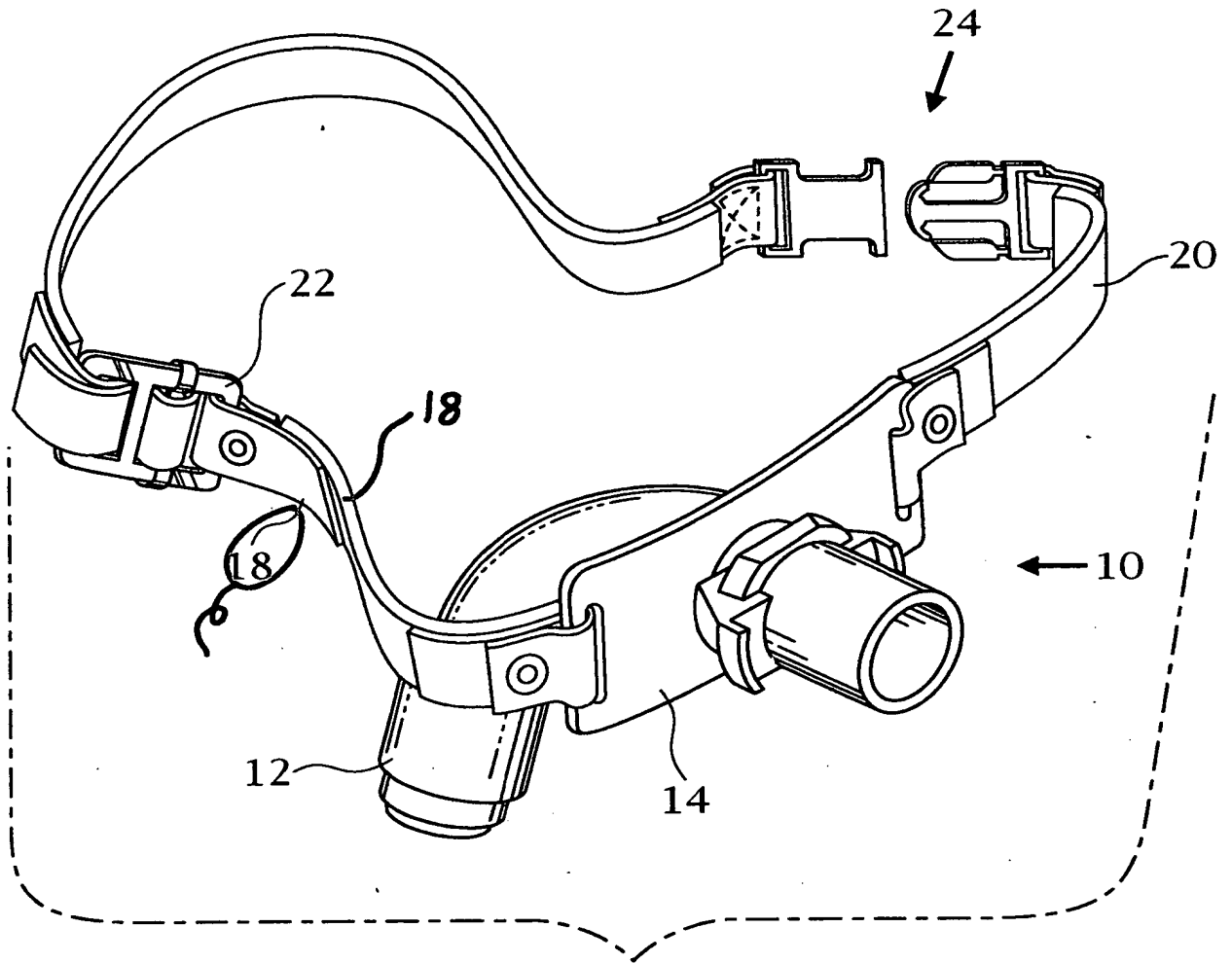


Fig 14

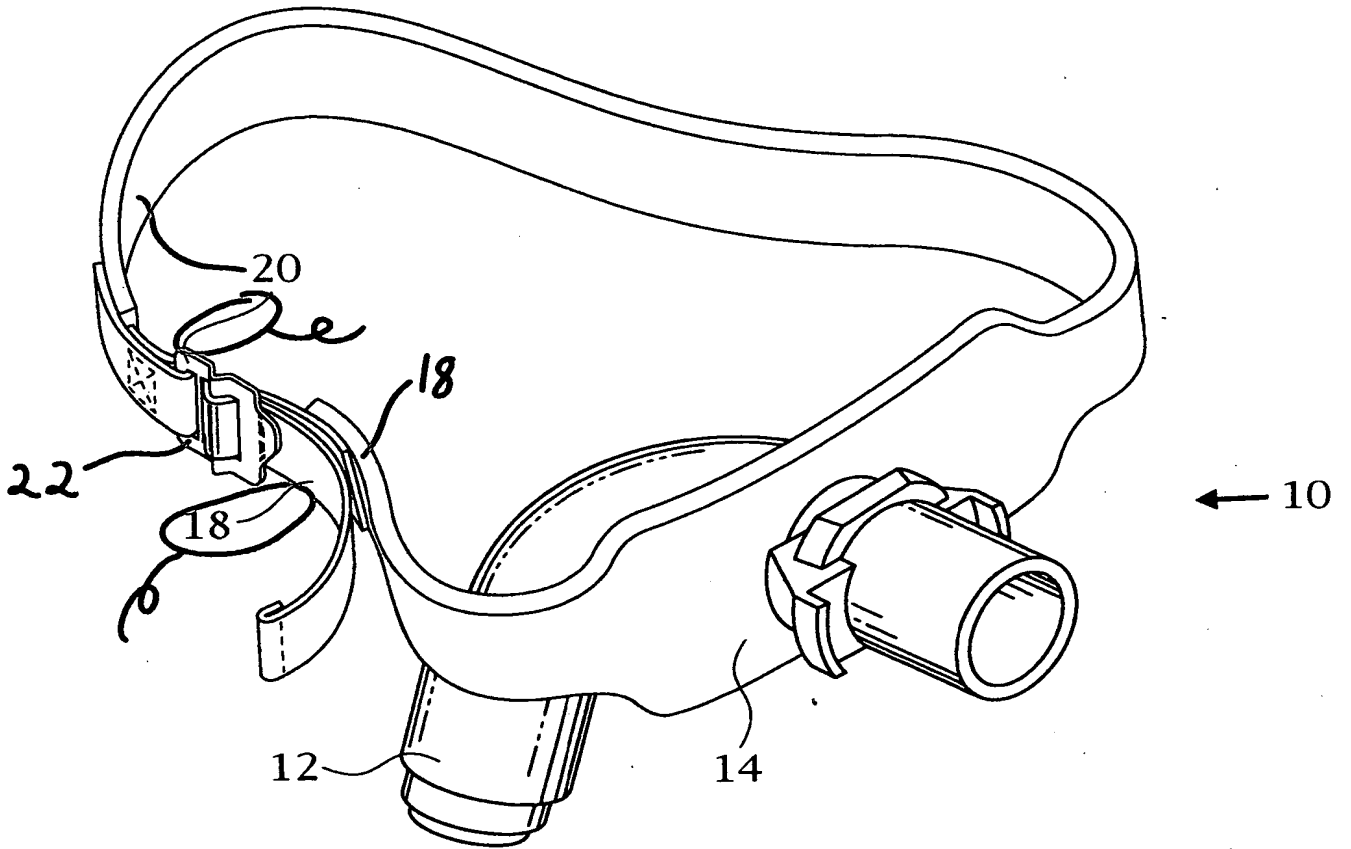


Fig 15

Fig 7

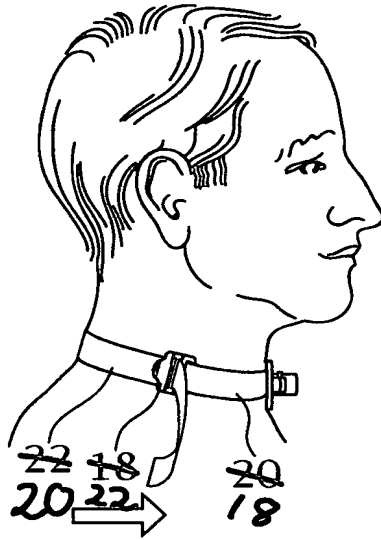


Fig 8

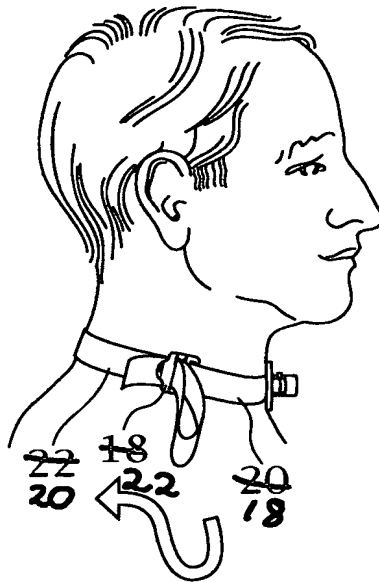
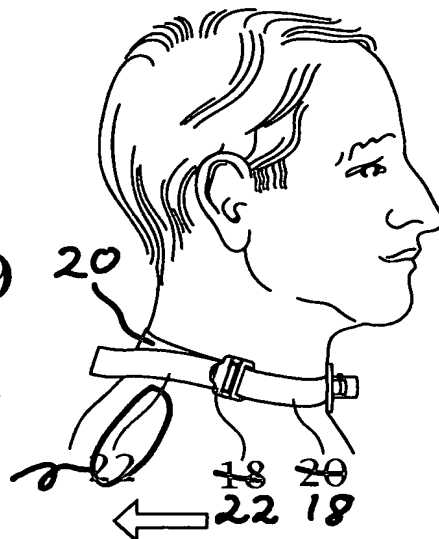


Fig 9



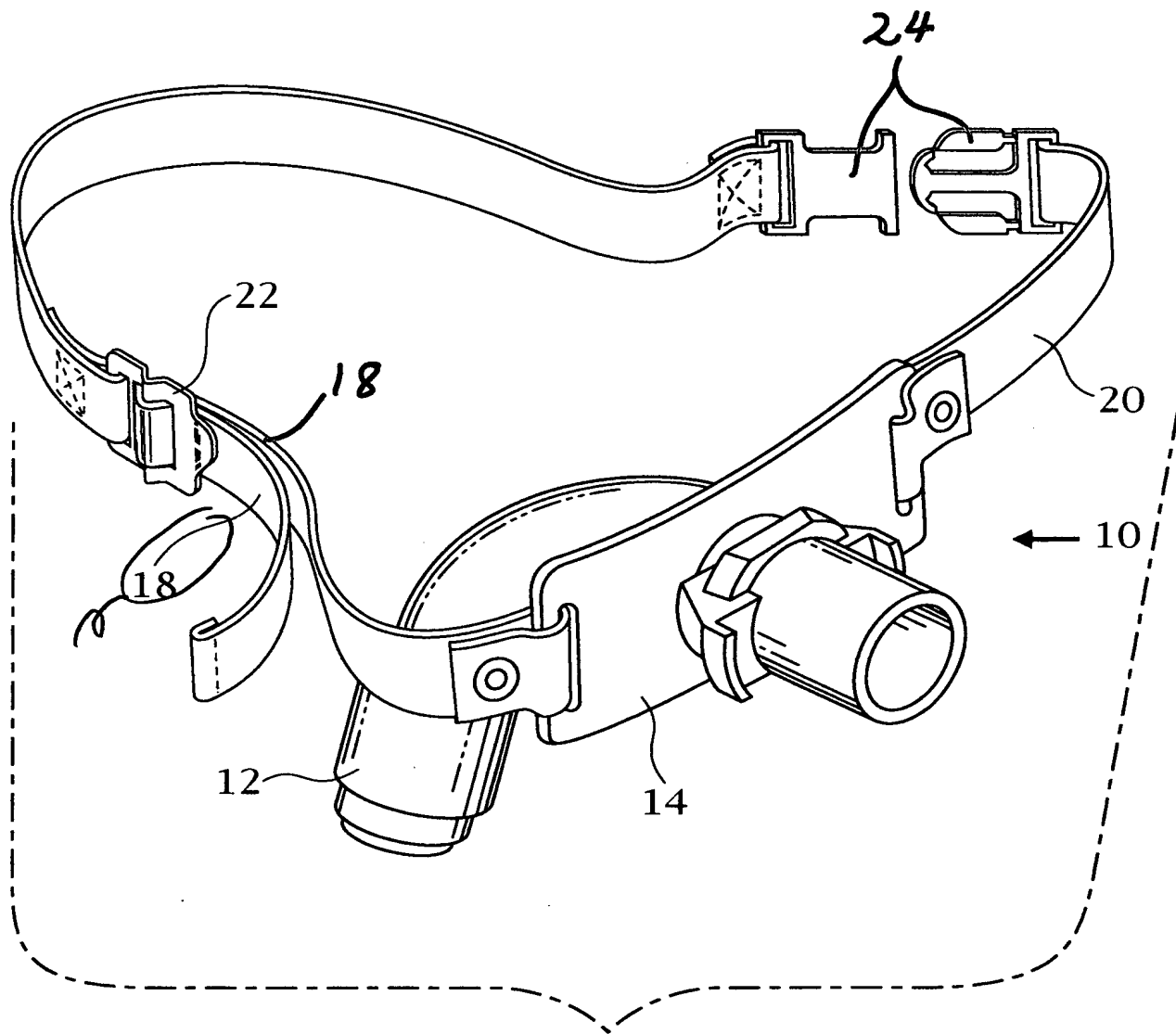


Fig 10

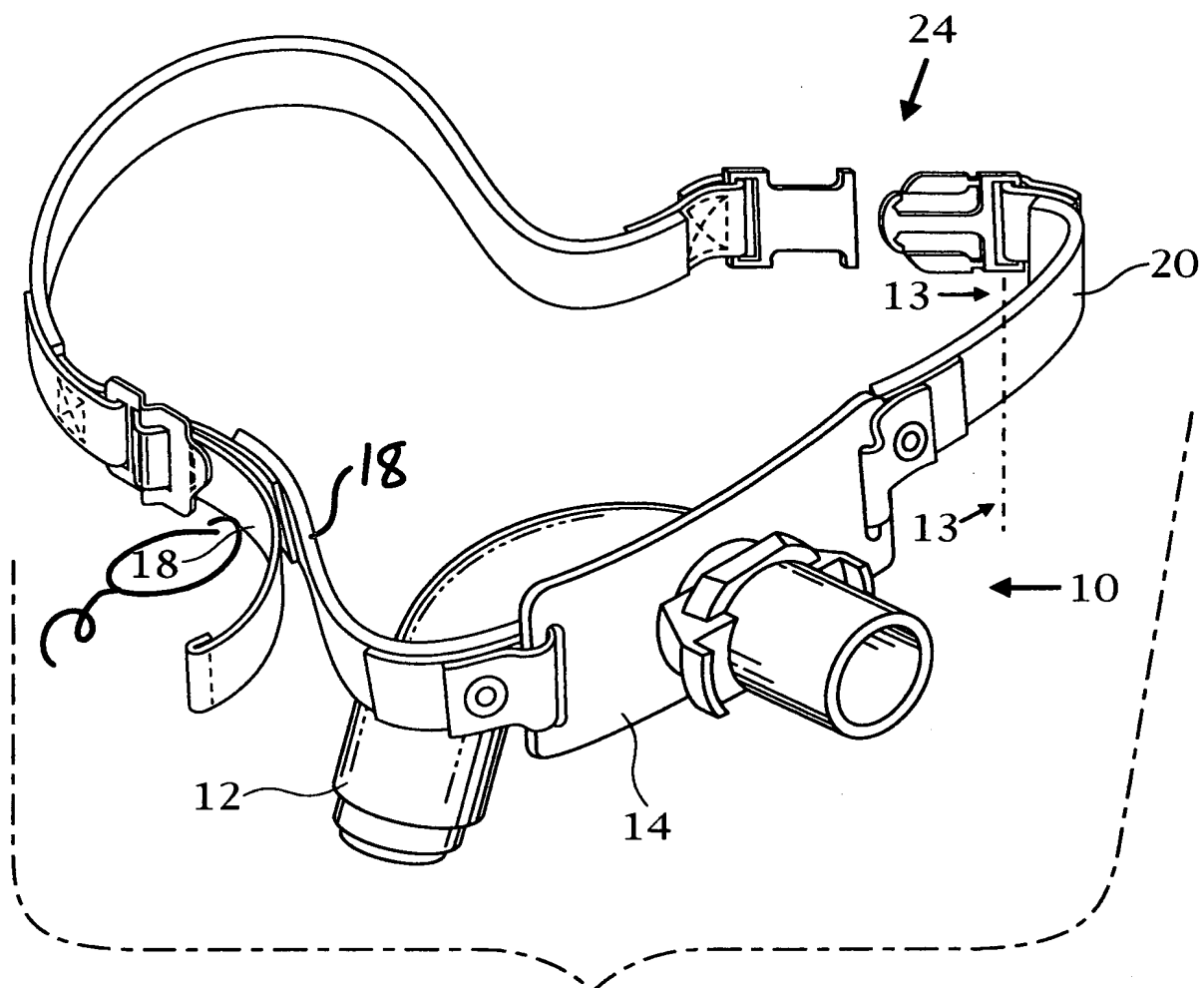


Fig 12

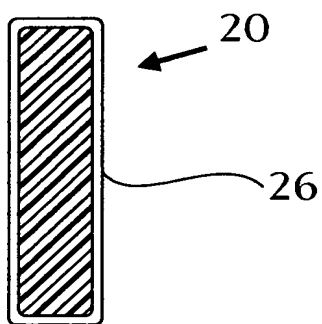


Fig 13

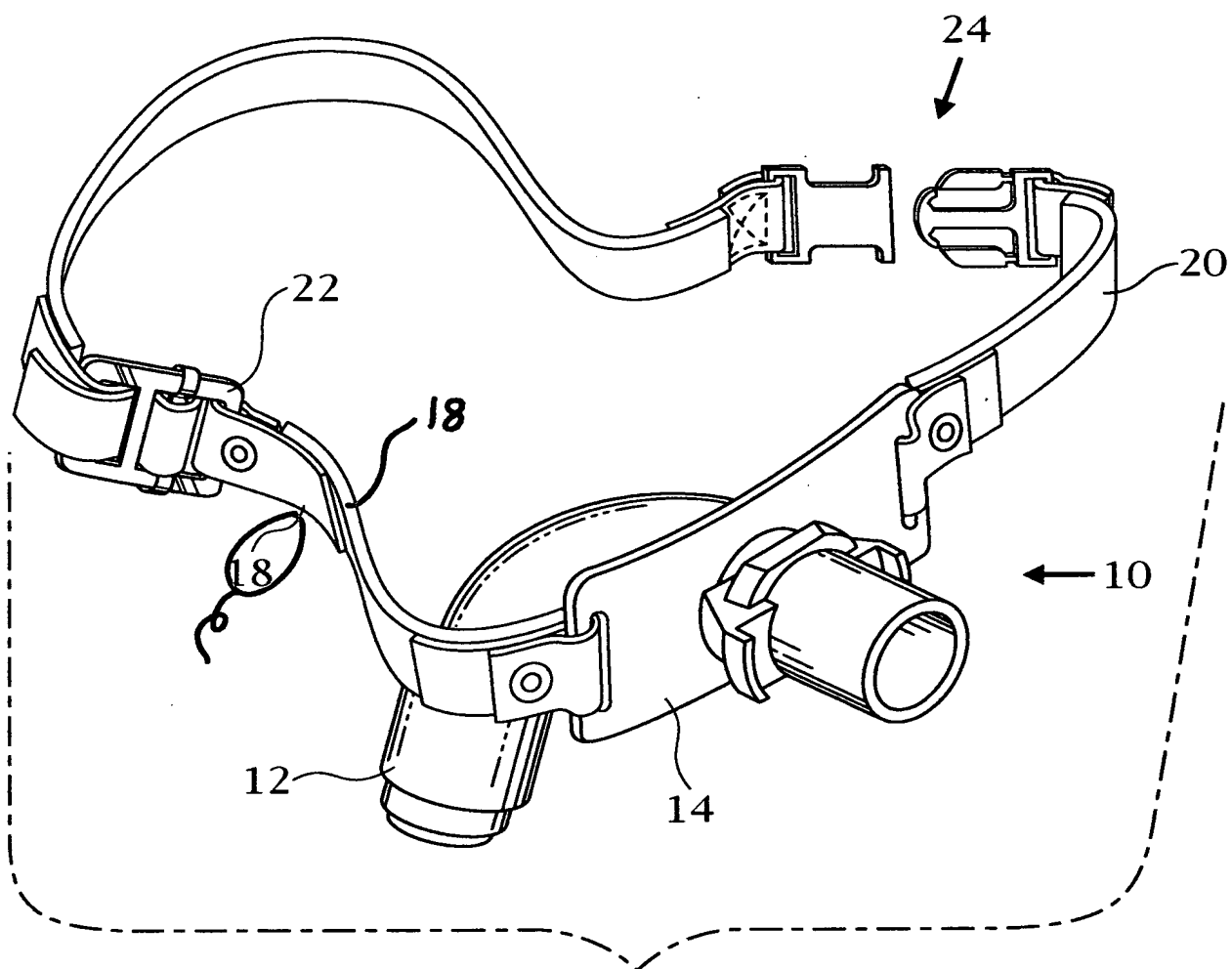


Fig 14

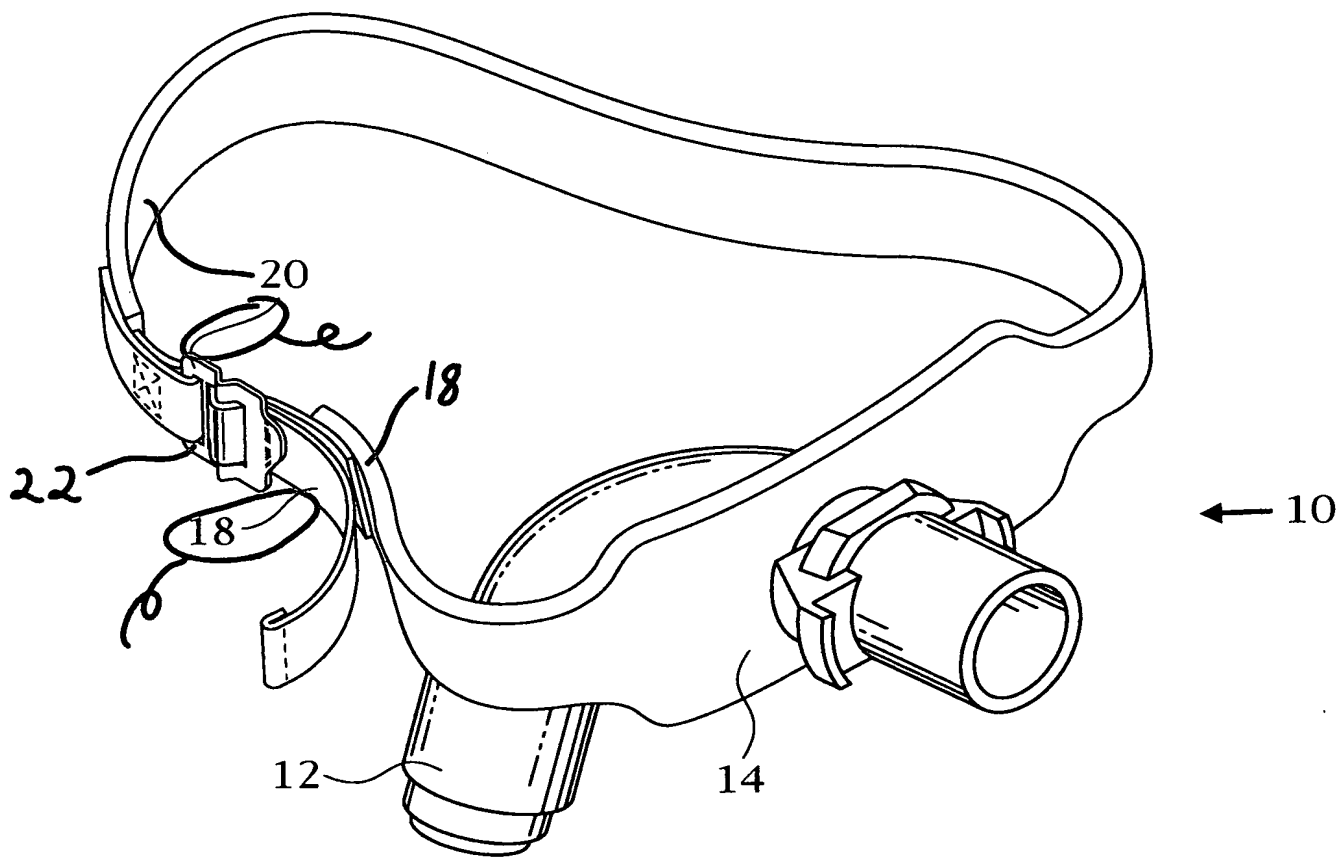


Fig 15